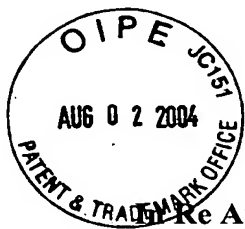


FW

DOCKET NO.: 3DP-0548/1610001

PATENT



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Re Application of:

Kevin D. Kreutter, et al.

Confirmation No.: 1002

Application No.: 10/816,544

Group Art Unit: 1646

Filing Date: April 1, 2004

Examiner: Not Yet Assigned

For: SUBSTITUTED PHENYL ACETAMIDES AND THEIR USE AS PROTEASE INHIBITORS

DATE OF DEPOSIT: July 29, 2004

I HEREBY CERTIFY THAT THIS PAPER IS BEING DEPOSITED WITH THE UNITED STATES POSTAL SERVICE AS FIRST CLASS MAIL, POSTAGE PREPAID, ON THE DATE INDICATED ABOVE AND IS ADDRESSED TO THE UNITED STATES PATENT AND TRADEMARK OFFICE, P.O. BOX 1450, ALEXANDRIA, VA 22313-1450.

TYPED NAME: Leslie E. Aberman  
REGISTRATION NO.: 54,836

Mail Stop Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

INFORMATION DISCLOSURE STATEMENT

Pursuant to 37 CFR § 1.56 and in accordance with 37 CFR §§ 1.97-1.98, information relating to the above-identified application is hereby disclosed. Inclusion of information in this statement is not to be construed as an admission that this information is material as that term is defined in 37 CFR § 1.56(b).

- ☒ In accordance with § 1.97(b), since this Information Disclosure Statement is being filed either within three months of the filing date of the above-identified application, within three months of the date of entry into the national stage of

the above identified application as set forth in § 1.491, before the mailing date of a first Office Action on the merits of the above-identified application, or before the mailing date of a first Office Action after the filing of request for continued examination under § 1.114, no additional fee is required.

☐ In accordance with § 1.129(a), this Information Disclosure Statement is being filed in connection with ☐ the first or ☐ second After Final Submission, therefore:

☐ Certification in Accordance with § 1.97(e) is attached; or

☐ The fee of \$180.00 as set forth in § 1.17(p) is attached.

☐ In accordance with § 1.97(c), this Information Disclosure Statement is being filed after the period set forth in § 1.97(b) above but before the mailing date of either a Final Action under § 1.113 or a Notice of Allowance under § 1.311, or before an action that otherwise closes prosecution in the application, therefore:

☐ Certification in Accordance with § 1.97(e) is attached;

or

☐ The fee of \$180.00 as set forth in § 1.17(p) is attached.

☐ In accordance with § 1.97(d), this Information Disclosure Statement is being filed after the mailing date of either a Final Action under § 1.113 or a Notice of Allowance under § 1.311 but before, or simultaneously with, the payment of the Issue Fee, therefore included are: Certification in Accordance with § 1.97(e); and the submission fee of \$180.00 as set forth in § 1.17(p).

- ☐ Copies of each of the references listed on the attached Form PTO-1449 are enclosed herewith.
- ☒ Copies of references listed on the attached Form PTO-1449 are enclosed herewith
- ☒ Copies of references listed on the attached Form PTO 1449 are not required to be submitted pursuant to the June 30, 2003 recent revisions to 37 CFR § 1.98(a)(2)(i).

## EXCEPT THAT:

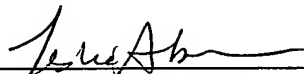
- ☐ In view of the voluminous nature of references [list as appropriate], and the likelihood that these references are available to the Examiner, copies are not enclosed herewith.
- ☐ In accordance with § 1.98(d), copies of the following references listed on the attached Form PTO-1449 are not enclosed herewith because they were previously cited by or submitted to the U.S. Patent and Trademark Office in patent application(s) for which a claim for priority under 35 U.S.C. § 120 have been made in the instant application:
- ☐ Copies of references [list as appropriate] listed on the attached Form PTO-1449 were previously cited by or submitted to the Patent and Trademark Office in prior Application No.

, filed .

Please charge any deficiency or credit any overpayment to Deposit Account No. 23-3050. This form is submitted in duplicate.

There are no listed references which are not in the English language.

Date: July 29, 2004

  
\_\_\_\_\_  
Leslie E. Aberman  
Registration No. 54,836

WOODCOCK WASHBURN LLP  
One Liberty Place - 46th Floor  
Philadelphia, PA 19103  
Telephone: (215) 568-3100  
Facsimile: (215) 568-3439



Sheet 1 of 5

<b>Form PTO-1449 Modified</b>  List of Patent and Publications Cited by Applicant (Use several sheets if necessary)  U.S. Department of Commerce Patent and Trademark Office	Docket No. <b>3DP-0548/1610001</b>	Application No. <b>10/816,544</b>
	Applicant <b>Kevin D. Kreutter, et al.</b>	
	Filing Date <b>April 1, 2004</b>	Group <b>1646</b>
	Confirmation No. <b>1002</b>	
<b>OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)</b>		
	<b>1</b>	Ashwood, M.S. et al., "Copper-Mediated Reaction of 2-Halopyridines with Ethyl Bromodifluoroacetate", <i>Tetrahedron Letters</i> , <b>2002</b> , 43, 9271-9273
	<b>2</b>	Baugh, R.J. et al., "Human Leukocyte Granule Elastase: Rapid Isolation and Characterization", <i>Biochemistry</i> , <b>1979</b> , 15(4), 836-841
	<b>3</b>	Bergeron, R.J. et al., "Total Synthesis of (+)-15-Deoxyspergualin", <i>J. Org. Chem.</i> , <b>1987</b> , 52, 1700-1703
	<b>4</b>	Bernatowicz, M.S. et al., "Urethane Protected Derivatives of 1-Guanylpurazole for the Mild and Efficient Preparation of Guanidines", <i>Tetrahedron Letters</i> , <b>1993</b> , 34(21), 3389-3392
	<b>5</b>	Claeson, G., "Synthetic Peptides and Peptidomimetics as Substrates and Inhibitors of Thrombin and Other Proteases in the Blood Coagulation System", <i>Blood Coagulation and Fibrinolysis</i> , <b>1994</b> , 5, 411-436
	<b>6</b>	Clagett-Dame, M et al., "Preparation of an Affinity Chromatography Matrix for the Selective Purification of the Dopamine D2 Receptor from Bovine Striatal Membranes", <i>Biochim. Biophys. Acta</i> , <b>1989</b> , 986, 271-280
	<b>7</b>	Coughlin, S.R., "Molecular Mechanisms of Thrombin Signaling", <i>Seminars in Hematology</i> , <b>1994</b> , 31(4), 270-277
	<b>8</b>	Cuyper, H.T. et al., "Sulfhydryl Content of Bovine Eye Lens Leucine Aminopeptidase", <i>The Journal of Biological Chemistry</i> , <b>1982</b> , 257(12), 7086-7091
	<b>9</b>	Dalcanale, E. et al., "Selective Oxidation of Aldehydes to Carboxylic Acids with Sodium Chlorite-Hydrogen Peroxide", <i>J. Org. Chem.</i> , <b>1986</b> , 51, 567-569
<b>EXAMINER</b>		<b>DATE CONSIDERED</b>

<b>Form PTO-1449 Modified</b>  List of Patent and Publications Cited by Applicant (Use several sheets if necessary)  U.S. Department of Commerce Patent and Trademark Office		Docket No. <b>3DP-0548/1610001</b>	Application No. <b>10/816,544</b>
		Applicant <b>Kevin D. Kreutter, et al.</b>	
		Filing Date <b>April 1, 2004</b>	Group <b>1646</b>
		Confirmation No. <b>1002</b>	
<b>OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)</b>			
	<b>10</b>	de Roos, A. et al., "Myocardial Infarct Sizing and Assessment of Reperfusion by Magnetic Resonance Imaging: A Review", <i>International Journal of Cardiac Imaging</i> , <b>1991</b> , 7, 133-138	
	<b>11</b>	Eto, H. et al., "New Antifungal, 1,2,4-Triazoles with Difluoro(heteroaryl) Methyl Moiety", <i>Chem Pharm Bull.</i> , <b>2000</b> , 48, 982-990	
	<b>12</b>	Feng, D.M. et al., "Discovery of a Novel, Selective, and Orally Bioavailable Class of Thrombin Inhibitors Incorporating Aminopyridyl Moieties at the P1 Position", <i>J. Med Chem</i> , <b>1997</b> , 40, 3726-3733	
	<b>13</b>	Harker, L.A., "Strategies for Inhibiting the Effects of Thrombin", <i>Blood Coagulation and Fibrinolysis 5 (Suppl 1)</i> , <b>1994</b> , S47-S64	
	<b>14</b>	Khaw, B.A. et al., "Myocardial Infarct Imaging of Antibodies to Canine Cardiac Myosin with Indium-111-Diethylentriamine Pentaacetic Acid", <i>Science</i> , <b>1980</b> , 209, 295-297	
	<b>15</b>	Lefkovits, J. et al., "Direct Thrombin Inhibitors in Cardiovascular Medicine", <i>Circulation</i> , <b>1994</b> , 90(3), 1522-1536	
	<b>16</b>	Mitsunobu, O., "The Use of Diethyl Azodicarboxylate and Triphenylphosphine in Synthesis and Transformation of Natural Products", <i>Synthesis</i> , <b>1981</b> , 1, 1-28	
	<b>17</b>	Powers, W.J. et al., "Indium-111 Platelet Scintigraphy in Cerebrovascular Disease", <i>Neurology</i> , <b>1982</b> , 32, 938-943	
	<b>18</b>	Sanderson, P.E.J. et al., "Efficacious, Orally Bioavailable Thrombin Inhibitors Based on 3-Aminopyridinone or 3-Aminopyrazinone Acetamide Peptidomimetic Templates", <i>J. Med Chem</i> , <b>1998</b> , 41, 4466-4474	
	<b>19</b>	Sato, K. et al., "Synthesis of Alkenyl-and Aryldifluoroacetate Using a Copper Complex from Ethyl Bromodifluoroacetate", <i>Chem. Pharm Bull.</i> , <b>1999</b> , 47(7), 1013-1016	
<b>EXAMINER</b>		<b>DATE CONSIDERED</b>	

<b>Form PTO-1449 Modified</b>  List of Patent and Publications Cited by Applicant (Use several sheets if necessary)  U.S. Department of Commerce Patent and Trademark Office		Docket No. <b>3DP-0548/1610001</b>	Application No. <b>10/816,544</b>
		Applicant <b>Kevin D. Kreutter, et al.</b>	
		Filing Date <b>April 1, 2004</b>	Group <b>1646</b>
		Confirmation No. <b>1002</b>	
<b>OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)</b>			
	<b>20</b>	Saulnier, M.G. et al. "An Efficient Method for the Synthesis of Guanidino Prodrugs", <i>Bioorganic &amp; Medicinal Chemistry Letters</i> , <b>1994</b> , 4(16), 1985-1990	
	<b>21</b>	Szilagyi, G. et al., "Synthesis and Antihypertensive Activity of Novel 6-Substituted-3-Pyridazinylhydrazones", <i>European J. Med. Chem.</i> , <b>1984</b> , 19(2), 111-117	
	<b>22</b>	Thakur, M.L. et al., "Indium-111 Labeled Platelets: Studies on Preparation and Evaluation of In Vitro and In Vivo Functions", <i>Thrombosis Research.</i> , <b>1976</b> , 9, 345-357	
	<b>23</b>	Tillyer, R. et al., "Efficient Synthesis of $\alpha$ -Chloro Ketones via Reaction of Organometallic Reagents with N-Methoxy-N-Methylchloroacetamide, <i>Synlett</i> , <b>1996</b> , 225-226	
	<b>24</b>	<i>United States Pharmacopeia/ National Formulary-USP</i> , <b>1995</b> , United States Pharmacopeial Convention, Inc., Rockville, Maryland, p 1636	
<b>EXAMINER</b>		<b>DATE CONSIDERED</b>	

<b>Form PTO-1449 Modified</b>  List of Patent and Publications Cited by Applicant (Use several sheets if necessary)  U.S. Department of Commerce Patent and Trademark Office	Docket No. <b>3DP-0548/1610001</b>	Application No. <b>10/816,544</b>
	Applicant <b>Kevin D. Kreutter, et al.</b>	
	Filing Date <b>April 1, 2004</b>	Group <b>1646</b>
	Confirmation No. <b>1002</b>	

### U. S. PATENT DOCUMENTS

Examiner Initial		Document No.	Date	Name	Class	Subclass
	25	4,418,052	11/29/83	Wong	424	1.1
	26	4,499,082	02/12/85	Shenvi, et al.	514	2
	27	4,652,440	03/24/87	Paik, et al.	424	1.1
	28	4,727,064	02/23/88	Pitha	514	58
	29	4,764,604	08/16/88	Muller	536	103
	30	4,957,939	09/18/90	Gries, et al.	514	492
	31	4,980,148	12/25/90	Dean	424	9
	32	5,011,686	04/30/91	Pang	424	94.1
	33	5,024,829	06/18/91	Berger, et al.	424	1.1
	34	5,024,998	06/18/91	Bodor	514	58

### FOREIGN PATENT DOCUMENTS

Examiner Initial		Document No.	Date	Country	Translation	
					YES	NO
	35	CA 2 164 684	06/14/96	Canada		
	36	EP 0 470 578 A1	02/12/92	EPO		
	37	EP 0 604 022 A1	06/29/94	EPO		
	38	EP 0 761 521 B1	12/06/00	EPO		
	39	WO 96/11668	04/25/96	PCT		

<b>EXAMINER</b>	<b>DATE CONSIDERED</b>
-----------------	------------------------



**Form PTO-1449 Modified**

List of Patent and Publications  
Cited by Applicant  
(Use several sheets if necessary)

U.S. Department of Commerce  
Patent and Trademark Office

Docket No.  
**3DP-0548/1610001**

Application No.  
**10/816,544**

Applicant  
**Kevin D. Kreutter, et al.**

Filing Date  
**April 1, 2004**

Group  
**1646**

Confirmation No.  
**1002**

**U. S. PATENT DOCUMENTS**

Examiner Initial		Document No.	Date	Name	Class	Subclass
	40	5,122,361	06/16/92	Kung, et al.	424	1.1
	41	5,466,811	11/14/95	Alexander	546	283
	42	5,656,600	08/12/97	Abelman, et al.	514	13
	43	5,786,515	07/28/98	Dolling, et al.	568	316

**FOREIGN PATENT DOCUMENTS**

Examiner Initial		Document No.	Date	Country	Translation	
					YES	NO
	44	WO 96/32143	10/17/96	PCT		
	45	WO 96/38136	12/05/96	PCT		

**EXAMINER****DATE CONSIDERED**